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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,111	06/02/2000	Rory A.J. Curtis	MNI-062CP2DV1	6800

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/587,111

Applicant(s)
Curtis

Examiner
John Ulm

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 30, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-49 is/are pending in the application.
- 4a) Of the above, claim(s) 28, 30, 38, 40, 47, and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 29, 31-37, 39, 41-46, and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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1) Claims 27 to 49 are pending in the instant application. Claims 1 to 19 and 22 to 26 have been canceled and claims 46 to 49 have been added as requested by Applicant in Paper Number 13, filed 30 September of 2002.

2) Claims 28, 30, 38, 40, 47, and 49, and claims 32 to 36 and 42 to 45 in so far as they depend from any of claims 28, 30, 38, 40, are directed to an invention that is independent or distinct from the invention originally claimed for those reasons of record in section 2 of Paper Number 11. Accordingly, these claims stand withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Applicant's argument that each of SEQ ID NO:5 and SEQ ID NO:20 are splice variants of a common protein is not persuasive because they are structurally distinct compounds and, therefore, in the absence of Applicant's admission that each is obvious over the other, the restriction is maintained.

3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5) Claims 46 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims require "a polypeptide that is 95% identical to the amino acid sequence of SEQ ID NO:5". It is clear that the limitation "95%", as employed in these claims, is not a

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range limitation or a minimum or maximum end-point value. Therefore these claims require one to make a polypeptide having an amino acid sequence that is 95% identical SEQ ID NO:5. To produce such a polypeptide entails changing **exactly** one out of every twenty amino acids in SEQ ID NO:5. However, SEQ ID NO:5 is 764 amino acid residues in length. Because 764 is not divisible by 20 by a whole number and because neither the instant specification nor the art of record discloses a process whereby one of ordinary skill can change a fraction of an amino acid residue, one can not practice the claimed method.

6) Claim 31, 41, 46 and 48, as well as claims 32 to 36 and 42 to 45 in so far as they depend from either of claims 31 and 41, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the practice of a method of identifying a ligand which binds to a receptor protein comprising the amino acid sequence presented in SEQ ID NO:5 of the instant specification, does not reasonably provide enablement for the practice of a binding assay which employs a protein having anything less than the entire amino acid sequence presented in SEQ ID NO:5 for those reasons of record. Applicant's arguments in traversal of this rejection essentially repeat those arguments of record which have been answered on the record.

Applicant urges that SEQ ID NO:20 is an example of a functional protein described in the instant specification which lacks the amino acid sequence SEQ ID NO:5. The original rejection stated that the instant specification does not provide "even a single working example of a functional protein lacking its entire native amino acid sequence". SEQ ID NO:20 of the instant application is the amino acid sequence of a naturally occurring protein and not the sequence of a

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protein which has been intentionally modified. With respect to those fragments of SEQ ID NO:5 that were employed in antibody production, there was no binding assay described which employed the step of contacting a cell expressing those fragment with a test compound.

With respect to Applicant's assertion that the instant specification meets the written description guidelines referred to by Applicant in Paper Number 13, it is noted that the instant claims have been rejected for lack of enablement, not for lack of written description.

This rejection is further applied to claim 42 for those reasons of record. Applicant argues that one would be able to employ fragments of SEQ ID NO:5 in a yeast two-hybrid system to identify compounds which interact with those fragments. This is not persuasive because the instant specification does not identify those specific domains within SEQ ID NO:5 which perform functions of interest and which have been shown to be functional outside of the context of a complete protein. In so far as this claim encompasses a system employing only a soluble portion of the amino acid sequence SEQ ID NO:5, the instant specification does not disclose a practical utility which is to be realized from the identification of a protein which binds to a portion of that amino acid sequence if one does not have a reasonable expectation that the selected portion functions in the yeast two-hybrid system in a manner that is representative of the natural activities of that portion in its native environment.

7) Claims 27, 29, 31, 37, 39, 41, 46 and 48, as well as claims 32 to 34, 36 and 43 to 45 in so far as they depend from any of claims 27, 29, 31, 37, 39, 41, stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Julius et al. patent (6,335,180 B1). The amino

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acid sequence presented in SEQ ID NO:5 of the instant application is identical to the amino acid sequence presented in SEQ ID NO:36 of the Julius et al. patent.

The declaration filed on 30 September of 2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Julius et al. reference. Under 37 CFR 1.131 practice, proof of a utility must be shown if the reference discloses a utility. In re Wilkinson, 304 F.2d 673, 134 USPQ 171 (CCPA 1962); In re Moore, 444 F.2d 572, 170 USPQ 260 (CCPA 1971). Julius et al. (starting at line 30 of column 26) disclosed the utility of the protein described therein in an assay to detect capsaicin and related compounds in a sample, for example. Applicant's declaration does not show that Applicant had contemplated a specific utility for the proteins described therein before the filing of the Julius et al. application.

8) Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Julius et al. patent (6,335,180 B1). Because the Julius et al. patent disclosed the fact that the receptor described therein was naturally expressed in neuronal tissue (first paragraph, column 37) an artisan would have found it prima facie obvious to have expressed that protein recombinantly in a neuronal cell line to obtain a more authentic response by that receptor to a test compound.

9) Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over the Julius et al. patent (6,335,180 B1) in view of the Chien et al. publication (P.N.A.S. 88:9578-9582, 1991) for those reasons of record. This rejection is not in conflict with the enablement rejection above. As stated in *Ex parte Dash*, 27 USPQ2d 1481 (BdPatApp&Int, 1993) “[w]e are not unaware that we are sustaining rejections under lack of enablement based on reasons which also

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apply to the prior art” and “[i]f appellants overcome the lack of enablement of their claims, they will necessarily overcome the lack of enablement of the references”. All of the elements of the claimed invention were in the prior art, as was the motivation to combine them into the claimed invention. Further, the instant specification provides neither an element of predictability that was lacking from the prior art or the disclosure of unexpected results.

10) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

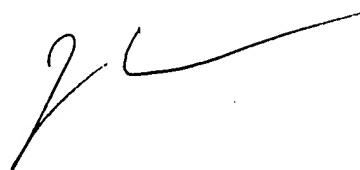
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Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306.
Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800